

U.S. Statement

Introduction

- Before I read out my prepared statement, let me first thank Zimbabwe, the Africa group and their co-sponsors as well as the E.C. for their thoughtful contributions to our discussions today. I believe Members will see in my statement that we share many of their views.
- The HIV/AIDS crisis is a terrible tragedy - for countries, families and individuals. The United States is fully committed to the battle against this disease.
- We very much want our discussion in this Council to make a constructive contribution to this effort.

I. Policy Points

- Our discussion today is intended to clarify Members' views of the interpretation and application of relevant provisions of the TRIPS Agreement, particularly with respect to -the flexibility Members have under the Agreement in providing access to life-saving drugs.
- The United States supports this discussion. We hope that, through this dialog, Members will come to appreciate the important role the TRIPS Agreement plays in stimulating development and commercialization of new life-saving drugs. We also hope that this dialog will result in a clearer understanding of existing flexibility in the Agreement which enables Members to ensure that such drugs are available to their citizens, particularly those who are unable to afford basic medical care.
- TRIPS strikes the proper balance between these two objectives. Some have quite incorrectly blamed the Agreement for health crises or claimed that it stands in the way of resolving such crises. Quite the contrary, Members have the ability under the Agreement to implement their obligations in a way that fully supports their national health care objectives.
- On the other hand, without the economic incentives provided by patent

systems, there would be far fewer drugs available for the treatment and cure of life-threatening diseases.

- My comments first address the United States' broader policy approach to fighting infectious diseases and life-threatening conditions. Strong patent, trademark, and trade secret protection is a key element because of the critical role such protection plays in the rapid innovation, development, and commercialization of safe and effective drugs.
- We are equally committed to ensure Members are able to use the flexibility in the Agreement where necessary to meet their health care objectives. In February, the Bush Administration reaffirmed the commitment of the United States to a flexible approach on health and intellectual property. Under this policy, we have informed WTO Members that, as they take steps to address major health crises, such as the HIV/AIDS crisis in sub-Saharan Africa and elsewhere, the United States would raise no objection if Members availed themselves of the flexibility afforded by the WTO TRIPS Agreement.
- A comprehensive approach is needed to serious health problems. We believe that participants in our discussion today should keep in mind that the TRIPS Agreement – its obligations and flexibility – is, at most, one element of the equation. To deal with serious health problems, countries need to stress education and prevention as well as care and treatment if health crises are to be eliminated.
- Health experts inform us that the cost of drugs is only one of many important issues that must be addressed in any health crises. Effective drug treatment necessitates urgent action to strengthen health management systems particularly directed to drug distribution and patient monitoring. Appropriate drug selection policies and standard treatment guidelines; training of care providers at all levels; adequate laboratory support to diagnose and monitor complex therapies; and systems for ensuring that the right drugs are used for the right purpose and in the right amount are all required to address the HIV/AIDS crisis.
- We must recognize that even if enough drugs to treat every single HIV positive person were provided, free of charge, an adequate infrastructure to

deliver them and monitor their use does not appear to exist in many areas most in need. To ensure that healthcare is available, particularly to those unable to afford basic medical care, health experts tell us that each country must also develop its medical and public health infrastructure, increase the resources allocated to health care, and take other appropriate steps.¹

- That is why the United States will continue to pursue an integrated approach to fighting disease, focusing on prevention of new infections and training medical professionals, as well as on treatment and care.
- As tangible evidence of our commitment to this integrated approach to fighting disease around the world, the United States continues to be the largest bilateral donor of HIV/AIDS assistance, providing for nearly 50% of all international HIV/AIDS funding.
- Recently, the United States announced a proposal for the creation of a new global fund to fight HIV/AIDS, malaria and tuberculosis. The United States will back this international effort by providing \$200 million in seed money for FY2002 . The United States also will work with other governments, private foundations, corporations, faith-based groups, and other organizations to generate additional support for this global effort. Just today, it was announced that the Gates foundation has made a major contribution of the fund.
- In addition to the \$200 million commitment to the new Global Fund, the United States budget for FY 2001 increases funding to fight the international

¹ At the Norway conference, Dr. Bundtland closed with the following statements:

- “We have head quite clearly that the price of drugs matters, it matters to poor people, and it matters to poor countries. But little progress will be possible without a significant investment in building effective health systems.”, and
- “There were other important lessons that came out of our review of current experience. It reinforced the point that just making drugs available - even at no cost - does not guarantee that they will be utilized. All other pieces of the picture have to be in place as well: the distribution systems, the partnerships between public and private providers; the agreements between governments and development agencies; and clear and explicit goals and objectives.

HIV/AIDS epidemic to \$480 million, increases to \$10.2 billion the budget of the department of Health and Human Services, and \$2.5 billion for the National Institutes of Health for HIV/AIDS research.

- My government invites the participation of other nations and other partners in securing the necessary funding to address the global HIV/AIDS pandemic.

A. Role of IPR in Developing New Healthcare-Related Technologies

- Recognizing that it is but one part of a much larger equation, let me focus on the role of intellectual property, particularly patents, in supporting effective health care.
- There is no question that patent systems serve public health objectives by stimulating discovery, development and commercialization of new products to prevent, treat, or cure illness.
- Specifically, the experience of the United States has been that a period of market exclusivity for innovated products and processes -- whether provided by a patent, data exclusivity, trade secrets or a combination of these legal protections - is essential to ensure development and commercialization of new healthcare products including pharmaceuticals, diagnostic products and medical devices.
- Without a period during which unauthorized parties cannot sell copies of the protected invention, the private sector may be unwilling to take the immense risks associated with development of significant new healthcare products. Market exclusivity for the results of innovation, not simply the possibility of a royalty, provides the necessary incentive for companies to invest in research to discover, develop and commercialize new products.
- Contrary to what many have asserted, this exclusivity does not give right holders a monopoly. In fact, the scope of the exclusivity provided by a patent is quite narrow. Based in part on the disclosure associated with the patent application, even during the patent term, competitive manufacturers are able to develop and market their own competing drugs to treat the same illness, ensuring price competition and a wide choice of effective treatments

for both doctors and patients.

- We understand that in the United States alone there are presently more than 100 new drugs for the treatment of HIV/AIDS in development, more than 120 new drugs to treat heart disease and stroke, more than 135 new drugs for treating or preventing infectious diseases, more than 400 new drugs for treating or curing cancers, and more than 700 new drugs to address diseases associated with aging.
- These are in addition to the revolutionary treatments that have been marketed in recent years that, every day, are saving lives that would have been lost just a few short years ago.
- Many thousands of initially promising drugs never reach the market because they have been found to be ineffective or too toxic. It is the prospect of market exclusivity that continues to spur the development and commercialization of new products despite the high number of unsuccessful compounds.
- Simply put, intellectual property protection systems, particularly patents and trade secrets, under the TRIPS model must be available to create the environment necessary for new drug development. This is significantly different from an environment that merely promotes copying of existing drugs.
- UN Secretary General Annan pointed this out recently, when he said, "Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people. The United Nations fully supports the TRIPS agreement -- including the safeguards incorporated within it."
- We also note that the Resolutions approved by at the May 21 World Health Assembly clearly recognize the importance of intellectual property in urging members to support, encourage and provide incentives for increased investment in research related to HIV/AIDS, including in the development of new preventive and therapeutic approaches and technologies, including in particular HIV/AIDS vaccines and microbicides."

- Apart from stimulating innovation, however, a strong IPR regime – particularly a strong patent regime – can also produce other benefits for countries, regardless of whether the countries are developed or developing.
- For example, countries that have strong patent regimes are more effective in attracting investments and market entry by innovative companies. The reasons for this are fairly simple. Patents provide a greater capacity for the innovator to compete based on the innovation. If the innovator cannot use the innovation to provide a market advantage, there is a disincentive to enter the market, particularly where others in that market can charge lower prices because they do not need to recover the costs of research and development, nor invest in new research and development.
- As I have already noted, another important benefit of a patent regime is that, in order to obtain a patent, an innovator must disclose all the technical details of the invention, a requirement embodied in TRIPs Article 29. This disclosure stimulates a significant flow of information to the public, including competing manufactures, that might otherwise be kept secret. Therefore, patent systems do not impede research and development activities nor do they discourage competition. Patent systems encourage this activity.
- Thus, patent regimes actually promote the objective of TRIPs Article 7 by contributing to the promotion of technological innovation and to the transfer and dissemination of technology.

II. TRIPS Reflects the Proper Balance Between Innovation and Access to Healthcare

- In establishing standards for patent regimes, and in providing certain flexibilities, the TRIPS Agreement has struck a proper balance between offering incentives for innovation and ensuring that there is access to needed medicines.
- Indeed, two documents available on the WTO website, the “WTO Fact Sheet: TRIPS and Pharmaceutical Patents,” and the “Technical Note: Pharmaceutical Patents and the TRIPS Agreement,” highlight how this

balance is struck by the Agreement. We encourage Members to refer to these documents as useful explanations of the Agreement and to avoid documents circulated by other individuals and organizations that lack the WTO's expertise.

- We also want to note the European Communities' thoughtful paper on the relationship between the provisions of the TRIPS Agreement and access to pharmaceuticals. We find many areas of agreement with them and note with interest some of the questions raised about "permissive" readings of Article 31.
- Before discussing the specific articles of the Agreement most commonly associated with access to medicine, I would like to remind delegations that among the most significant flexibilities contained in the TRIPS Agreement are the transition periods provided to developing and least developing country Members, especially the specific transition period provided to Members which had not established patent protection for pharmaceuticals and agricultural chemicals at the time the Agreement entered into force.
- We would like to understand better what impact the TRIPS Agreement could be having on the health care regimes of least developed country Members given that these Members are not currently obligated to implement the Agreement, including its patent provisions. We are particularly interested because certain Members have suggested that these transition periods be further extended, even before these Members have had any experience implementing the Agreement.

A. Article 30 of TRIPS

- Article 30 of the TRIPS Agreement allows Members to provide for limited exceptions to exclusive patent rights so long as the exceptions do not unreasonably conflict with the normal exploitation of the patent or prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.
- Earlier drafts of the Article reveal that negotiators had in mind exceptions for such things as so-called prior user rights; acts done privately and for non-

commercial purposes; acts done for experimental purposes; and similar activities.

- We note that a panel considered Article 30 in a dispute between the European Communities and Canada, regarding the provision of Canada's patent law allowing generic manufacturers to make use of patented drugs during the patent term solely for the purpose of developing data to obtain marketing approval for a generic equivalent. This policy was designed to allow introduction of generic drugs on the market quickly after the expiration of the patent. The panel found that the exception in Canada's law, with one exception, was sufficiently limited to fall within the scope of Article 30.
- That means that exceptions for pre-expiration testing similar to those provided in Canada and the United States which significantly accelerate the availability of lower cost generic drugs can be included in Members' patent laws without violating the Members' obligations under the TRIPS Agreement. This is an important flexibility in the Agreement that enhances access to drugs.

B. Article 31 of TRIPS

- It is apparent that Article 31 creates obligations for Members only when a particular pharmaceutical is protected by a patent within its territory. It should be obvious that Members have no TRIPS obligations with respect to products that are not protected by patents within their territories, even though those products are patented elsewhere.
- Therefore, it is not necessary for a Member to grant a compulsory license to produce a pharmaceutical product within its territory if patent protection for that pharmaceutical product does not exist in its territory.
- As has been noted by the European Communities and others, Article 31 does not itemize the purposes for which compulsory licenses may be granted. Instead, the Article establishes conditions that must be met with respect to compulsory licenses, conditions that are modified, in some instances, depending upon the purpose for which the compulsory license was granted.

- Of course, article 31 must be read in light of the other provisions of the TRIPs Agreement, including Article 27.1. The latter provision prohibits discrimination in the enjoyment of patent rights based on whether products are imported or domestically produced. In other words, importation of a product, rather than domestic production, cannot justify the grant of a compulsory license.
- Because Article 31 does not specify the circumstances under which compulsory licenses may be granted it is understandable that it does not make express reference to public health. Article 8.1 makes it clear, however, that public health is one concern Members may take measures to address, so long as the measures are consistent with the TRIPS Agreement's provisions.
- While I will not discuss in detail each of the conditions established by Article 31, I would like to highlight those that seem most relevant for our discussion today.
- The second condition under Article 31 establishes an obligation, then provides circumstances in which that obligation may be waived. The obligation is that unauthorized use may be permitted only if the party seeking a compulsory license has been unable, within a reasonable period of time, to obtain a voluntary license on reasonable commercial terms and conditions.
- That obligation may be waived in a national emergency or other circumstances of extreme urgency or in the case of public non-commercial use. This waiver authority is, of course, very important for our discussion today.
- The possibility of waiver recognizes that, in the case of a national emergency or other circumstances of extreme urgency, there isn't time to enter into negotiations with a patent owner to obtain a voluntary license. Certainly, epidemics such as HIV/AIDS within a Member's territory are as much a national emergency or a circumstance of extreme urgency as war, civil strife, or natural disasters for purposes of exercising the waiver authority. The United Nations Security Council made this point last year.

- Paragraph (b) also permits a waiver of the requirement to seek a voluntary license first in the case of public non-commercial use, recognizing that requiring governments to do patent searches and seek voluntary licenses before every procurement of goods or services for the government's own use would delay the procurement of those goods or services and would add to their costs.
- Paragraph (b) also makes clear, however, that in cases in which the requirement to seek a voluntary license is waived, the patentees must be notified as soon as reasonably practicable. In addition, paragraph (h) of Article 31 makes it clear that the patentees must be paid adequate remuneration for the use of their patents, taking into account the value of the authorization.
- Paragraph (c) specifies that the scope of a compulsory license and its duration are to be limited to the purpose for which the license was authorized. Obviously, were such a license granted on a patented drug in order to address a condition of extreme urgency, such as an epidemic, the use should be limited to providing the pharmaceutical to treat those suffering from the disease or to prevent contraction of the disease, if that is the purpose of the pharmaceutical. The duration would likely depend upon the duration of the epidemic. Related to this, paragraph (g) provides for the termination of compulsory licenses when the circumstances that led to its issuance cease to exist and are unlikely to recur.
- Paragraph (f) is also very important for our discussion today, because questions have been raised about whether a compulsory license can be granted under a patent to a supplier from another country. Paragraph (f) states that compulsory licenses should be authorized predominantly for supply of the domestic market of the Member authorizing the use.
- In our view, the nationality of the recipient of a compulsory license is not relevant for purposes of Article 31. What is relevant, in such a case, would be whether the license results in infringement of a patent for the same product in the licensee's country.
- Obviously, if no patent for the drug has been granted in the licensee's

country, no infringement would occur. If such protection does exist, however, and the compulsory licensee chooses to manufacture the drug in its country for export to the country that granted the compulsory license, a problem is created. If the patentee successfully sued the producer in the other country, the compulsory license originally granted would be ineffective in supplying of the needed pharmaceutical.

- For this reason, one must consider whether it would be appropriate to limit eligibility for compulsory licenses to those parties that can assure the government granting the license that they will be able to supply the market without interruption that might result from infringement of a patent in their own country.
- The non-national could make such assurances either because no patent existed in its home country, because it had obtained a voluntary license from the patentee in its home country that allowed it to produce the patented pharmaceutical for the supply of the other market, or because it planned to produce the patented pharmaceutical in the territory of the country granting the compulsory license.
- The EC has identified a possible interpretation of the agreement with respect to whether a compulsory license can be granted under a patent to a supplier from another country even where patent infringement might otherwise be considered to have occurred. This proposal raises questions that should be addressed if there is further discussion of this concept.
- Lastly, I would like to address two misconceptions regarding compulsory licensing. First, contrary to what some have asserted, compulsory licenses under TRIPS are not intended to be a mechanism for directing industrial development, protecting domestic industries against foreign competitors, or for promoting the now widely discredited economic policy of import substitution.
- The foundation of free trade embodied in the WTO system is the removal of conditions that lead to inefficiencies in global trade. The WTO has long recognized the trade-distorting nature of local content, import substitution and local production requirements. We note that the non-discrimination

clause of Article 27.1 of the TRIPS Agreement is built on this foundation.

- Pharmaceuticals are among the best examples of products where these principles are true. Pharmaceuticals can be efficiently produced in a small number of locations and transported through international trade to markets needing those products. Such efficiencies in production and distribution lead to lower prices and faster supply of products to meet demands, including those caused by public health emergencies.
- Indeed, recent studies have shown that local production does not necessarily result in lower prices.
- Second, Some have observed that certain Members employ compulsory licenses to remedy anti-competitive practices, as the TRIPS Agreement clearly provides, with no ill effect to their patent system.
- Certainly the United States has never suggested that compulsory licenses are not a fully appropriate and TRIPS-consistent way to remedy anti-competitive behavior. However, we would point out that compulsory licenses are used in this manner to remedy an abuse, and not in the normal course of doing business. Therefore, it is inaccurate to suggest that U.S. practice would support the conclusion that there would be no negative implications for patent systems, and more importantly incentives for developing future life-saving drugs if Members were to permit widespread use of compulsory licences for any purpose.

C. Parallel Imports

- So-called “parallel imports” are also sometimes raised in discussions regarding access to drugs. To be clear, we define that term to mean legitimate goods produced by a patent owner or with the patent owner’s authorization that are purchased in one market where the price is attractive, whether as the result of differential pricing by the patentee in recognition of the economic development of a country, of currency differences, of price controls, etc., and imported into another country where a patent exists, without the authorization of the patent owner.

- There is no question that Article 6 denies Members the ability to avail themselves of dispute settlement in relation to questions involving parallel imports, except when those questions involve national or most favored nation treatment. However, Article 6 of the TRIPS Agreement does not, in our view, authorize parallel imports. Members must remember that Article 6 does not alter the substantive obligations of the TRIPS Agreement, particularly those contained in Part II of the Agreement.
- In our view, advocates of parallel importation overlook the fact that permitting such imports discourages patent owners from pricing their products differently in different markets based upon the level of economic development because of the likelihood that, for example, products sold for low prices in a poor country will be bought up by middle men and sent to wealthiest country markets and sold at higher prices, for the benefit primarily of the middle men.
- The lack of parallel import protection can also have significant health and safety implications. Our law enforcement and regulatory agencies, especially FDA, have commented on how very difficult it is for them to keep counterfeit and unapproved drugs out of our country even with the strong parallel import protection provided in the United States.
- Advocating parallel imports, therefore, could work to the disadvantage of the very people on behalf of whom the advocates purport to be speaking. As Dr. Brundtland in Oslo recently noted, “For differential pricing to work on a large scale, I think we can all agree that there must be watertight ways of preventing lower priced drugs from finding their way back into rich country markets.”

D. Article 39.3

- With respect to Article 39.3, we concur with the EC’s observation that the most effective way of protecting test data against “unfair commercial use” in a manner consistent with the TRIPS Agreement is to ensure that regulatory authorities do not rely on such data for a reasonable period of time, such as five years, as is the case in the United States.

III. Conclusion

- To conclude, I believe it is universally agreed that we must provide incentives for investment in research and development of new and more effective life saving drugs. Effective patent systems, therefore, are crucial if we are to find better treatments and ultimately cures for HIV/AIDS and the many other diseases and health conditions that afflict the world's population.
- The TRIPS Agreement appropriately requires that an effective patent system be provided within every WTO Member. It also provides sufficient flexibility by allowing certain limitations on patent rights to, among other things, address public health issues, including diseases and conditions that are epidemic and endemic.
- We look forward to the interventions of other delegations, the in depth analysis behind such interventions, particularly in those cases where it is being asserted that TRIPS is not sufficiently flexible, and to continuing this discussion in future meetings.